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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,454	09/17/2003	Mark L. Jenson	760-68 RCE II	4333

23869 7590 01/22/2009
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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,454	JENSON, MARK L.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27 and 48-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27 and 48-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-15, 27, 48, 50, 54, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Houser et al. (US Pat. No. 6,149,681). Houser et al. discloses the following of the claimed invention as shown in Figure 42: a composite device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: a first polymeric liner (inner element 246); a second polymeric liner (outer element 246); an intermediate structural member or elongate stent (258) interposed between said first and said second polymeric liners, said intermediate structural member being defined by solid segments and openings therebetween such that the first liner is bonded to the second liner through said openings to form at least one pocket adjacent to said solid segments, said pocket being defined by said first and second liners, their area of direct bonding, and said solid segments; and a fluid containing a bioactive agent disposed within said pocket adjacent to said solid segments of said intermediate structural member (col. 3, lines 41-52). Houser et al. further discloses the limitations of claims 13-15 in col. 7, lines 50-58.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Rudakov et al. (US Pat. No. 6,451,050). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not teach encapsulating a bioactive agent in a polymeric matrix. Rudakov et al. teaches a stent where the bioactive agent is encapsulated in a polymeric matrix in col. 4, lines 40-50 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Rudakov et al., as shown in claim 11, further in view of Helmus et al. (US Pub. No. 2002/0032477). Houser et al., as modified by Rudakov et al., discloses the invention substantially as claimed, however, they do not teach constructing the polymeric matrix holding the bioactive agent of microparticles. Helmus et al. teaches a biological prosthesis that uses microparticles in the matrix in paragraph 0048 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claims 16 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Golds et al. (US Pat. No. 6,001,125). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not teach using porous ePTFE to construct the device. Golds et al. teaches a vascular graft constructed from porous ePTFE in columns 3 and 4 for the purpose of utilizing the material's enhanced radial strength of the less porous area and the enhanced cell endothelialization associated with the more porous area. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use porous ePTFE in order to utilize the material's radial strength and cell endothelialization.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Buirge et al. (US Pat. No. 5,693,085). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not teach using a natural polymer to construct the device. Buirge et al. teaches a biological prosthesis that uses a natural polymer to construct the device in col. 6, lines 10-28 for the purpose of providing biological protection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a natural polymer to construct the device in order to provide biological protection.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Yan (US Pat. No. 6,240,616). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not teach using a bioabsorbable polymer to construct the device. Yan teaches a biological prosthesis that uses a bioabsorbable polymer to construct the device in col. 9, lines 22-36 for the purpose of

delivering therapeutic agents to a damaged site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a bioabsorbable polymer to construct the device in order to deliver therapeutic agents to a damaged site in a patient.

Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Rhodes (US Pat. No. 5,665,117). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not teach using stainless steel or tantalum to construct the device. Rhodes teaches a biological prosthesis that uses stainless steel or tantalum to construct the device in col. 6, lines 8-30 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use stainless steel or tantalum to construct the device in order to utilize the material's biocompatibility.

Claim 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Yang (US Pub. No. 2002/0062147). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not teach using a gel to contain the bioactive agent. Yang teaches a biological prosthesis that uses a gel to contain the biological agent in paragraph 0073 for the purpose of retaining the drug in the device for a longer period of time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a gel to contain the bioactive agent in order to retain the drug in the device for a longer period of time.

Claim 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Wang et al. (US Pat. No. 6,458,867). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not teach pre-treating the pocket. Wang et al. teaches pre-treating medical devices in col. 12, lines 8-24 for the purpose of reducing any irritation caused by the device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pre-treat the device of Houser et al. in order to reduce any potential irritation it may cause.

Response to Arguments

Applicant's arguments filed 10/17/2008 have been fully considered but they are not persuasive. The Applicant contends that Houser et al. does not disclose the pocket being defined by the area of direct bonding between the first and second layers. The Applicant cited Figure 16 of Houser et al. to show this deficiency. However, the examiner has referred to Figure 42 as the embodiment that meets the claims' limitations both above and in the previous office action. It can be seen in Figure 42 that the pocket is defined by the inner and the outer layers (246), the structural member/stent (258), and the area of direct bonding between the layers.

The Applicant further contends that Houser et al. does not disclose the pocket containing drugs in conjunction with the cited disclosure. It is unclear which disclosure the Applicant is referring to in the arguments (Figure 16 or Figure 42). In addition, Houser et al. states that the pockets may contain drugs in col. 3, lines 41-52. The language of the reference does not indicate that this function is tied to only one

particular embodiment of the invention, and all of the pockets disclosed would be fully capable of holding the drugs.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner, Art Unit 3774